John M. Sernulka
President and CEO

May 25, 2007

David A. Neumann, PhD, Health Policy Analyst
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, Maryland 21215

Re: Request for Informal Public Comment on Draft Regulations – COMAR 10.24.05, Research Waiver Applications for Participation in the Atlantic Cardiovascular Patient Outcomes Research Team Study of Non-Primary Percutaneous Coronary Interventions Performed in Maryland Hospitals without On-Site Cardiac Surgery

Dear Dr. Neumann:

Carroll Hospital Center (CHC) is pleased to provide these comments on the draft regulations for Waiver Applications for non-primary PCI performed in Maryland hospitals without on-site cardiac surgery.

A representative from our hospital participated on the Interventional Cardiology Subcommittee of the Commission's Advisory Committee on Outcome Assessment in Cardiovascular Care that met between September 2002 and April, 2003. Over the past several years, we have consistently supported and advocated for Maryland's participation in a well-designed research study (the Atlantic Cardiovascular Patient Outcomes Research Team Study in particular) to determine whether non-primary PCI performed in hospitals without on-site cardiac surgery services is as safe and effective as non-primary PCI performed in hospitals with on-site cardiac surgery services. Participation in this important research will maintain our State's position as a leader in developing world renowned healthcare best practices (as in the C-Port primary PCI study) and to advance the development of lifesaving measures for those suffering a cardiac event.

The Commission has undertaken an exhaustive review of this study, including having the study reviewed by the Commission's expert Research Proposal Review Committee, spanning more than two years before approving the establishment of a waiver process to participate in the study. As this study is already underway in several other states where similar, patient centered, rigorous review also took place, we can be further reassured of the safety and appropriateness of this clinical trial. The Commission's rigorous review process and that undertaken by these other states leave no doubt that this study is sound,

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contains stringent quality control standards, high expectations to assure best clinical practice, a patient centered quality approach, and strict participation standards.

Given the rigorous review that this study has undergone and the importance of this research, we are concerned that the proposed limit of only six hospitals is unnecessary and counter-productive. The existing waiver process for participation in primary angioplasty intrinsically establishes a limit setting process. We question the need to further complicate the system and delay the advancement of sound science by establishing a study participation limit in addition to the participation guidelines in the existing primary PCI waiver.

We believe that any Maryland hospital that meets the required performance standards and that participates in the primary PCI waiver program should be offered the opportunity to participate in the study. Limiting the number of hospitals with a waiver for primary PCI that can participate in the study creates a second tier of approval which seems unnecessary. This would be similar to not allowing open heart programs to perform cardiac valve surgery. By adding additional patient volume to the existing programs, the proposed new study patient volumes could be met sooner and access to PCI services would be more equitable.

By limiting the number of participating hospitals providing non-primary PCI the MHCC is limiting the opportunity for best practices as well as limiting the number of patients from Maryland who can participate in the study. In fact, other states, such as Tennessee and Wisconsin, allow hospitals to perform non-primary PCI first so that they can select their cases, adequately train staff and hone their skills before moving to primary PCI cases.

Any concern regarding capital expense associated with establishing facilities, equipment etc., necessary to participate in the study is not presented for hospitals already participating in the primary PCI waiver. In fact, it is probably not an issue for most of the top quality Maryland hospitals. The facilities required most likely already exist, as they do at Carroll Hospital Center. Highly skilled, specialty vessel intervention procedures to relieve vascular obstructions in other critical organs are performed in these same interventional laboratory settings.

Additionally, the Commission should allow hospitals not currently participating in the primary PCI waiver but that receive a primary PCI waiver in the future to participate in this study. As the MHCC currently has a waiver process in place for primary angioplasty, and there is a schedule to file applications for that waiver, other hospitals that are approved for primary angioplasty should be granted the opportunity to participate in this landmark clinical trial. Participation in advanced clinical research such as the primary PCI C-Port study, have enhanced American medical care; indeed have allowed the developmental progression of so many procedures considered impossible in our very recent past. Continued pursuit and participation by interested, qualified practitioners is essential.

We are hopeful that you will incorporate these changes in the draft regulations. As always, we look forward to the prospect of additional dialogue and appreciate the opportunity to comment on these draft regulations.

Sincerely,

John Sernulka
President and CEO